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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
3771	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,255	PFLUEGER ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *91-110* is/are rejected.

7)☒ Claim(s) *93* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/11/06 & 1/6/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to applicant's preliminary amendment filed June 9, 2005. As directed by the preliminary amendment, claims 1-90 have been cancelled and claims 91-110 have been added. Thus, claims 91-110 are pending in this application.

Information Disclosure Statement

2. The information disclosure statement filed August 11, 2006 fails to comply with 37 CFR 1.98(a)(2), **which requires a legible copy of each cited foreign patent document;** each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information lined through has not been considered.

3. The information disclosure statement filed August 11, 2008 fails to comply with 37 CFR 1.98(a)(3) **because it does not include a concise explanation of the relevance,** as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information lined through has not been considered.

Drawings

4. The drawings are objected to because the lines, numbers & letters are not uniformly thick and well defined. See: attached Notice of Draftsperson's Patent Drawing Review. Form PTO-948. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the

application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities: The use of the trademarks NITINOL™ in the abstract and in numerous places throughout the specification; SOMNOPLASTY™ on page 4, line 25; and REPOSE™ on page 5, line 13 has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

6. Claim 93 is objected to because of the following informalities: Claim 93 lacks a period. Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 91-103 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Where a claim is directed to an apparatus attached to the human body or any part thereof the claim is directed to nonstatutory subject matter because the claim positively recites part of a human body. See: 1077 Official Gazette, April 21, 1987.

Claims 91 and 100 are rejected because they positively recite parts of a human body. Claim 91 claims "extending generally laterally across the posterior wall and, when so placed, being effective in treating at least one of sleep apnea and snoring" in lines 1-13 and claim 100 claims "a constrained configuration for delivery into an oropharyngeal region, and an open configuration when the appliance is so placed in an oropharyngeal region" In lines 2-4.

This rejection can be obviated by claiming the device as "adapted to" be placed in or on a part of a human body.

Any remaining claims are rejected as depending from a rejected base claim.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 93, 96, 97, 103 and 110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 93 is confusing because it recites the limitation "the other elongated element" and "the at least one elongated element"; however, there is insufficient antecedent basis for this limitation in the claim. It is unclear if applicant is referring to the "at least one element" of claim 91, "the elements" of claim 92, or if "the other elongated element" and "the at least one elongated element" are referring to other elements all together.

Claims 96, 97 and 106 are rejected for reasons analogous to those of claim 93.

11. Claims 103 & 110 contains the trademark/trade name NITINOL™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or

trade name. In the present case, the trademark/trade name is used to identify/describe nickel titanium and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that forms the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 91, 94, 98, 104, and 107 are rejected under 35 U.S.C. 102(b) as being anticipated by Fege (DE19920114A1) based on the machine translation provided by the European Patent Office (EPO).

Regarding claim 91, Fege discloses an apparatus (46 & 52) for treating at least one of sleep apnea (obstructive sleep apnea syndrome (OSAS)) and snoring in a human (figures 1-3) or animal having an oropharyngeal (36) region with lateral and posterior walls, the apparatus (46 & 52) comprising: an appliance comprising at least one element (46 & 52) having a length extending from a first end (48 & 54) to a second end (50 & 56), the at least one element being substantially bow shaped (figures 1-3 and third to last paragraph on page 2 of the Description machine translation provided by EPO) with the appliance at rest (last paragraph of page 1 of the Description machine translation provided by EPO), the appliance being sized and structured to be placed in (figures 1-3) or radially outwardly from the lateral and posterior walls of an oropharyngeal region (36) of a human or animal with the length of the at least one element (46 & 52) extending generally laterally across (figures 1-3) the posterior wall

and, when so placed, being effective in treating at least one of sleep apnea (OSAS) and snoring.

Regarding claim 94, Fege discloses at least one bow shaped element (46 & 52) extending from first end (48 & 54) to second end (50 & 56) through less than about 50% of an arc of a circle (see 46 &52 which are less than 50% of an arch of a circle) with the appliance at rest.

Regarding claim 98, Fege discloses an appliance (46 & 52) has a lateral dimension defined by the distance between the first (48 & 54) and second (50 & 56) ends and a maximum longitudinal (figure 2 & 3) dimension perpendicular to the lateral dimension which is less than the lateral dimension.

Regarding claim 104, Fege discloses a method for treating at least one of sleep apnea (OSAS) and snoring in a human (figures 1-3) or an animal having an oropharyngeal region (36) with lateral and posterior walls, the method comprising: providing an appliance (46, 52) in or radially outwardly from the lateral and posterior walls of the oropharyngeal region (best seen in figure 2) of the human or animal, the appliance comprising at least one element having a length extending from a first end (48 & 54) to a second end (50 & 56), the at least one element being substantially bow shaped (figures 1-3 and third to last paragraph on page 2 of the Description machine translation provided by EPO) with the appliance at rest, the appliance being provided so that the length of the at least one element extends generally laterally across the posterior wall of the oropharyngeal region. See: figures 1-3.

Regarding claim 107, Fege discloses placing (implanting) the appliance in or beneath the mucosal layer (figures 1-3 and page 2, lines 33-50 of the machine translation of the Description provided by EPO) of the lateral and posterior walls of the oropharyngeal region.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 92, 95, 100, 105 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fege (DE19920114A1) based on the machine translation provided by the European Patent Office (EPO).

Fege discloses all the limitations of instant claim 92 ad `105 except Fege lacks specifically describing how to couple together two elements wherein the respective first and second ends are spaced apart from each other. However, Fege teaches that "The implants 1 and 1' can become single and combined with one another or single or together combined with a tongue basic implant inserted, in particular if detected as substantial causes for the OSAS both dropping back of the tongue is and incidences of the throat side panels from the beginning. The choice of the implants depends on which structures substantial in the sleep collapsing." See: second to last paragraph on page 2 of the machine translation of the description provided by EPO and figures 2-3.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have coupled two elements together at respective first and second ends, as taught by Fege, in order to obtain a one piece sleep treatment implant device capable of treating OSAS caused by both the tongue dropping back into the throat and supporting the lateral edge of the tongue and the lateral portion of the throat.

Regarding claim 95, it is obvious from figures 2-3 that the at least two elements would be spaced apart from each other by a varying distance between the first and second ends when a one piece structure is formed as suggested by Fege.

Regarding claim 100 & 109, the implant device disclosed by Fege, is a convex, bow shaped apparatus formed of "grown, body-own tissue or of plastic or a combination of both materials" and would therefore provide for easy manipulation via pressing on the ends of the convex, bow shaped apparatus to allow a practitioner to place the implant in a patient's oral cavity and place them in a desired configuration for implantation. See: figures 1-3 and last paragraph on page 2 of the machine translation of the Description provided by EPO.

16. Claims 93, 96, 97 and 106, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Fege (DE19920114A1) based on the machine translation provided by the European Patent Office (EPO) and further in view of Knudson et al (2003/0149445).

Fege discloses all the limitations of claims 93, 96 and 106 except the at least one of the elements includes an outwardly extending region between the first and second

ends substantially further spaced apart from the other elongated element than any other region of the at least one elongated element.

Knudson teaches a device for providing pharyngeal airway support (figure 11) that has and outwardly extending region (26b) between the first (24b) and second ends (24b) which is maximally spaced apart from the ends of the elements (24b). See: page 4 [0069] and figures 1-12.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the OSAS device disclosed by Fege by utilizing an outwardly extending region, as taught by Knudson, in order to provide additional support to the lateral wall portions and to the posterior of the pharyngeal wall.

Regarding claim 97, Knudson discloses a device with two outwardly extending regions (figure 12) that are substantially centrally located between the first (24a) and second ends (24a), and extend in a substantially opposing direction relative to the other outwardly extending region. See: page 4 [0069] and figures 1-12.

17. Claims 99, 101-103 & 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fege (DE19920114A1) based on the machine translation provided by the European Patent Office (EPO) and further in view of Peterson (2002/0189727).

Fege discloses all the limitations of claims 99, 101-103 & 110 except the elements being made of a resilient wire (claim 99), a biocompatible metal (claim 101), an elastic spring memory material (claim 102), and NITINOL™ (claims 103 & 110).

Peterson teaches that NITINOL™ is a well known material in the art and has superb elasticity. Peterson teaches a method of training NITINOL™ wire to take the

form of any desired shape and that because of its inherent elasticity the NITINOL™ will spring back to its trained shape. See: page 1 [0003] & page 2 [0028].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the device disclosed by Fege out of NITINOL™, a well known, biocompatible material, as taught by Peterson, in order to obtain a device that could be deformed during surgical implantation and then return to its desired shape because of its inherent elasticity. Moreover, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sanders et al (5,290,289) & McNamara et al (5,147,370) teach implantable devices formed of NITINOL™; Grosbois et al (6,474,339); Boucher et al (2007/0192587); Dubrul et al (2004,0020492); Zammit (6,328,753); Freedman (5,176,618); Patil et al (5,720,275) teach devices that can be used to treat apnea and snoring.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771